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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/386,266	08/31/1999	DAVID J. BRAYDEN	99.1080.US	1219

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EXAMINER
DEVI, SARVAMANGALA J N

ART UNIT	PAPER NUMBER
1645	25

DATE MAILED: 05/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/386,266	Brayden
Examiner	**Art Unit**
S. Devi, Ph.D.	1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) [X] Responsive to communication(s) filed on *Mar 6, 2003* .

2a) [X] This action is **FINAL**. 2b) [] This action is non-final.

3) [] Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) [X] Claim(s) *1-6 and 15-20* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) [] Claim(s) _____ is/are allowed.

6) [X] Claim(s) *1-6 and 15-20* is/are rejected.

7) [] Claim(s) _____ is/are objected to.

8) [] Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) [] The specification is objected to by the Examiner.

10) [] The drawing(s) filed on _____ is/are a) [] accepted or b) [] objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) [] The proposed drawing correction filed on _____ is: a) [] approved b) [] disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) [] The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) [] Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) [] All b) [] Some* c) [] None of:

1. [] Certified copies of the priority documents have been received.
2. [] Certified copies of the priority documents have been received in Application No. _____ .
3. [] Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) [] Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) [] The translation of the foreign language provisional application has been received.

15) [X] Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) [] Notice of References Cited (PTO-892)
2) [] Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) [X] Information Disclosure Statement(s) (PTO-1449) Paper No(s). *24.*
4) [] Interview Summary (PTO-413) Paper No(s). _____
5) [] Notice of Informal Patent Application (PTO-152)
6) [] Other:

Continued Prosecution Application

1) The request filed on 03/06/2003 (paper no. 22) for a Continued Prosecution Application (C.P.A) under 37 C.F.R 1.53(d) based on parent Application, SN 09/386,266, is acceptable and a C.P.A has been established. An action on the C.P.A follows.

Applicant's Amendment

2) Acknowledgment is made of Applicant's amendment filed 03/06/03 (paper no. 23) in response to the final Office Action mailed 11/29/02 (paper no. 18).

Status of Claims

3) Claim 1 has been amended via the amendment filed 03/06/03.

Claims 1-6 and 15-20 are pending and are under examination.

Information Disclosure Statement

4) Acknowledgment is made of Applicant's Information Disclosure Statement filed 03/06/03 (paper no. 24). The information referred to therein has been considered and a signed copy is attached to this Office Action (paper no. 25).

Prior Citation of Title 35 Sections

5) The text of those sections of Title 35 U.S Code not included in this action can be found in a prior Office Action.

Prior Citation of References

6) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Rejection(s) Maintained

7) The rejection of claims 1-6 and 15-20 made in paragraph 12 of the Office Action mailed 11/29/02 (paper no. 18) under 35 U.S.C. § 112, first paragraph, as containing new subject matter, is maintained for reasons set forth therein and herebelow.

In response to the new matter rejection made for the addition of new matter to the base claims 1 and 15, Applicant states that they have corrected a typographical error by changing the recitation "a least' to 'at least' in claim 1. This correction of a typographical error does not

address the rejection, nor does it provide or point to the descriptive support in the specification for a method of inducing a **T_H1** polarised immune response to an antigen comprising parenteral administration to a subject of microparticles sized such that 'at least 50% of the microparticles are at least 0.6 μm **and** at least 50% of the microparticles are less than 5 μm" [Emphasis added]. 'Microparticles' that are 'at least 0.6 μm' in size are not supported in the specification as originally filed. A method of inducing a polarized T_H1 immune response to an antigen by parenterally administering to a subject microparticles with the now recited microparticle size combination was not contemplated in the instant specification, as originally filed.

Remarks

8) Claims 1-6 and 15-20 stand rejected.

9) This is a C.P.A of Applicant's earlier Application, SN 09/386,266. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Additionally, since no new rejections have been made in this Office Action, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicants are reminded of the extension of time policy as set forth in 37 C.F.R 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center's telephone

number is (703) 308-4242, which is able to receive transmissions 24 hours a day and 7 days a week. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

11) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

May, 2003

S. DEVI, PH.D.
PRIMARY EXAMINER